Biotech Daily

Tuesday April 19, 2022

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: NOVA EYE UP 10%; KAZIA DOWN 6%**

*** PROTAGONIST: FDA TO RESCIND RUSFERTIDE BREAKTHROUGH STATUS**

*** VOLPARA RECEIPTS UP 44.7% TO $26m**

*** ALCIDION: NT HEALTH $5m FOR MIYA PRECISION UPGRADE**

*** UNIVERSAL BIOSENSORS TN ANTIGEN CANCER TEST; FUNDING HALT**

*** BTC: FEDERAL METHODOLOGY 'POTENTIALLY INCONSISTENT'**

*** PHARMAUST RECEIVES $708k FEDERAL R&D TAX INCENTIVE**

*** IMMURON 'ELIGIBLE' FOR $5.4m US TRAVELAN FUNDING**

*** HERAMED, PEDIATRIX VIRTUAL OBSTETRICS PROGRAM 'PROMISING'**

*** STATE STREET TAKES 5% OF POLYNOVO**

MARKET REPORT

The Australian stock market was up 0.56 percent on Tuesday April 19, 2022, with the ASX200 up 41.8 points to 7,565.2 points. Twelve of the Biotech Daily Top 40 stocks were up, 14 fell, 12 traded unchanged and two were untraded. All three Big Caps fell.

Nova Eye was the best, up 2.5 cents or 9.8 percent to 28 cents, with 128,905 shares traded, followed by Imugene up 9.3 percent to 23.5 cents, with 23.1 million shares traded.

Resonance rose 8.7 percent; Actinogen climbed 4.5 percent; Amplia and Telix improved more than three percent; Alcidion rose 2.5 percent; Oncosil was up 1.7 percent; with Clinuvel, Nanosonics, Pro Medicus and Proteomics up by less than one percent.

Kazia led the falls, down 6.5 cents or 5.8 percent to $1.06, with 36,809 shares traded, followed by Avita down 5.5 percent to $2.05 with 692,271 shares traded.

Antisense, Impedimed, Paradigm and Starpharma fell four percent or more; Cynata lost 3.7 percent; Micro-X and Neuren shed more than two percent; Compumedics, CSL, Genetic Signatures, Opthea and Orthocell were down one percent or more; with Cochlear, Emvision and Resmed down by less than one percent.

PROTAGONIST THERAPEUTICS

Protagonist says the US Food and Drug Administration intends to rescind breakthrough status for rusfertide for polycythemia vera due to “observed malignancies”.

Brisbane’s Protagonist said that orphan drug and fast track designations remained in place for rusfertide, or PTG-300, its injectable peptide for rare blood disorders and it had “submitted a response and requested a meeting” with the US FDA.

In a Form 8-K current report, filed to the US Securities and Exchange Commission on April 13, 2022, Protagonist said it had “received a letter from … [the FDA] indicating the FDA’s intent to rescind breakthrough therapy designation for the company’s rusfertide product candidate in polycythemia vera”.

In an attached presentation, the company said that the FDA notified its intent to rescind the designation “based on observed malignancies, in follow-up to the FDA clinical hold imposed on September 16, 2021”.

Last year, Protagonist fell 62.0 percent to $US17.53 ($A24.08) following an FDA clinical hold on its rusfertide studies (BD: Sep 20, 2021).

In October, the company said the FDA had removed the hold and trials had resumed and its share price recovered 94 percent to $US35.36 ($A48.16) (BD: October 13, 2021).

Protagonist said at that time that it had notified the FDA of “benign and malignant subcutaneous skin tumors” observed in a 26-week “rasH2 transgenic mouse model” toxicology study.

“The rasH2 model is designed to detect signals related to tumorigenicity, and benign and malignant subcutaneous skin tumors were observed in this study,” the company said on its website.

Last week, Protagonist said in its US SEC filing that it had submitted a meeting request to the FDA, along with a briefing document articulating why it believed rusfertide continued to warrant breakthrough therapy designation.

Protagonist said that the FDA letter did not relate to the rusfertide fast track designation “which remains active”.

The company said that initiation of its rusfertide phase III study in polycythemia vera was underway and no changes to the development plan or timeline were anticipated at this stage.

Protagonist said it expected to announce top-line data from its phase II trial evaluating PN-943 for ulcerative colitis “in the first half of the second quarter of 2022” or by May 15.

On Thursday April 14, Protagonist fell 21.8 percent from $US25.52 ($A34.65) to $US19.95 with 4.9 million shares traded.

Overnight fell a further 76 US cents or 3.81 percent to $US19.19 with 1.2 million shares traded.

VOLPARA HEALTH TECHNOLOGIES

Volpara says its unaudited cash receipts for the twelve months to March 31, 2022 were up 44.7 percent to $NZ28,485,000 ($A26,052,447).

Volpara said its cash receipts came from the sales of its breast mammography software and subscription contracts.

The company said that its annual recurring revenue was up 13.98 percent to $NZ31.8m and that it had cash and cash equivalents of $NZ18,152,000 at March 31, 2022 compared to $NZ32,230,000 at March 31, 2021.

Volpara was unchanged at 88 cents.

ALCIDION GROUP

Alcidion says it has a $5 million, five-year agreement with Northern Territory Health to upgrade its Miya Precision platform for patient management.
Alcidion said the Darwin-based, NT Health had been a partner since 2009 and it would upgrade the Miya Precision platform from an earlier version.
The company said the contract was valued at $5.0 million over five years with the option of a two-year extension and would “support NT Health’s management of patient flow and bed management between major hospitals and satellites across the Northern Territory”.
Alcidion managing-director Kate Quirke said that the deployment of Miya Precision was “unique considering the geographically dispersed population supported by NT Health”.
Alcidion was up half a cent or 2.5 percent to 20.5 cents with 1.1 million shares traded.

UNIVERSAL BIOSENSORS

Universal Biosensors has requested a capital raising trading halt and says interim results show its Tn Antigen blood test is more accurate for cancer than existing approved tests.
Last year, Universal Biosensors said it would begin work on the finger-prick blood tests with the Bilbao, Spain-based Basurto University Hospital along with Melbourne’s Victorian Cancer Biobank (BD: Sep 20, 2021).
The company said at that time the study would include 280 patients with 160 prostate patient samples to be studied at Basurto University Hospital and 120 patient samples from the Victorian Cancer Biobank including 40 breast, 40 prostate and 40 colorectal.
Today, Universal Biosensors said Tn Antigen was “potentially more sensitive and more specific” than the carcino-embryonic antigen (CEA) biomarker for monitoring colorectal cancer and the prostate-specific antigen (PSA) biomarker for monitoring prostate cancer.
Universal Biosensors said that it analyzed 76 samples and for colorectal cancer, its two-electrode test strip had 100 percent sensitivity and 60.0 percent specificity, its three-electrode strip had 100 percent sensitivity and 90.0 percent specificity, while the CEA had 55.2 percent sensitivity and 83.6 percent specificity.
The company said that for prostate cancer its two-electrode test strip had 92.9 percent sensitivity and 60.0 percent specificity, its three-electrode strip had 72.7 percent sensitivity and 90.0 percent specificity, while the PSA had 85.4 percent sensitivity and 30.3 percent specificity.
Universal Biosensors said the study consisted of 66 retrospective subjects from three tumor streams, colorectal, prostate and breast, and 10 cancer-free control subjects and that while the sample sizes were not statistically significant, they gave it “confidence in the Tn Antigen product and that there [are] significant improvements to be achieved through continued development of the chemistry and three-electrode strip”.
The company said the Tn Antigen program was expected to enter clinical trials in mid-2023 and finish in mid-2024, with registration expected by early-2025.
Universal Biosensors chief executive officer John Sharman said that the Tn Antigen platform had “the potential to materially improve the way in which patients and physicians monitor changes to cancer tumors in a point-of-care setting, using our hand-held analyzer and a finger prick of whole blood”.
“This first set of results from our development clinical study are extremely promising and reinforces our confidence in moving on with the commercialization of this product,” Mr Sharman said. “Importantly our development work continues, and we are confident we can deliver an even better performance from the Tn Antigen biosensor than results achieved to date indicate.”
Universal Biosensors was in a trading halt and last traded at 78.5 cents.

BTC HEALTH

BTC Health says that the Federal Department of Health's reduction in Prosthesis List benefits is "potentially inconsistent with the agreed methodology".
BTC said that specifically the assessment of its ambulatory drug-delivery infusion pumps was "potentially inconsistent with the agreed methodology as set out in the memorandum of understanding between the Minister of Health and the Medical Technology Association of Australia."
The company said that the Department of Health had released a proposed reduction in Prostheses List benefits from July 1, 2022, including a "closing of pricing differences between medical devices in the public and private sectors".
BTC said that "under the agreed methodology no benefit reductions should apply".
BTC chair Dr Richard Treagus said that "we have engaged directly with the [Department] to clarify the methodology that has been applied in relation to our Ambit infusion pumps".
BTC fell 0.2 cents or 3.2 percent to six cents.

PHARMAUST

Pharmaust says it has received $708,113 from the Australia Tax Office under the Federal Government Research and Development Tax Incentive program.
Pharmaust said the rebate related to research and development expenditure for the year to June 30, 2021.
Pharmaust fell 0.4 cents or 4.35 percent to 8.8 cents.

IMMURON

Immuron says its request for $US4 million ($A5.4 million) for Travelan for diarrhoea from the US Department of Defence has been considered "eligible for award".
Immuron said it was attempting to have Travelan for preventing travelers' diarrhoea approved by the US Food and Drug Administration through a biologics licence application.
Earlier this year, the company said it had received $US4.45 million from the US Department of Defence for the development of a military dosing regimen of Travelan for diarrhoea (BD: Jan 16, 2022).
Today, Immuron said it was seeking the additional $US4 million "to fund the investigational new drug application, chemistry, manufacturing and controls assay development and validation, non-clinical safety studies and stability studies required to support the [biologics licence application]".
Immuron said the new project was to develop a self-administered, non-vaccine, oral immunotherapy to prevent endemic diarrhoeal disease by targeting multiple bacterial pathogens such as Escherichia coli, which should "mitigate symptoms, shorten the duration of illness, and/or reduce the risk of contracting bacterial diarrheal illnesses".
The company said that it had been "formally notified" that no government funding was immediately available but the application had been deemed "eligible for funding" for a period of up to two years.
Immuron chief executive officer Dr Jerry Kanellos said that the project funded in January was "reviewed similarly and was funded six months post eligibility notification".
"There is also the potential for additional non-competitive funding for follow-on tasks from this request for prototype proposal to partially support the planned phase III pivotal registration clinical studies depending on the success of the project," Dr Kanellos said.
Immuron was unchanged at 10.5 cents.

HERAMED

Heramed says its virtual obstetrics program with Pediatrix Medical Group using its foetal heartbeat monitor has been “well-received” by patients and providers.

Heramed said the pilot study, at the Sunrise, Florida-based Pediatrix’ practice aimed to “shift the care model from the traditional 12 to 14 in-office visits to a hybrid model of in-office and telemedicine visits coupled with remote patient monitoring”.

The company said that the goals of the pilot program were to evaluate the patient and provider experience, and demonstrate the ‘non-inferiority’ of care, and patient and provider willingness to evolve how they receive and provide care.

Heramed said that patients were provided with access to connected devices, including its Herabeat foetal heart rate doppler, a blood pressure cuff and a scale, and asked to measure their vital signs and emotional health as well as read educational information, which was then uploaded to the Heracare clinician-facing population management dashboard.

Heramed said that patients reported “excellent satisfaction scores of 4.3” of a maximum of 5.0, both patients and providers reported satisfaction with the connected care model and that outcomes were “equal or superior to standard care model outcomes in preliminary analysis”.

The company said that patients in the virtual program captured “more than 2.5 times as many vital measurements compared to traditional maternity care” and had a reduction in the number of their office visits.

Heramed said that “given the promising findings to date, the partnership will continue to offer Virtual [obstetrics] care as an official program to low-risk maternity patients” and it had plans to expand its program with Pediatrix to include further care plans for other cases, such as postpartum care.

Heramed was unchanged at 16 cents.

POLYNOVO

State Street and its subsidiaries, says it has become a substantial share-holder in Polynovo with 33,248,594 shares or 5.02 percent.

The Boston-based State Street said that between December 13, 2021 and April 13, 2022 it bought, transferred and returned shares, with the single largest purchase on December 31, 2021 of 418,028 shares for $639,583 or $1.53 a share.

Polynovo was unchanged at $1.11 with 3.1 million shares traded.